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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,408	10/01/2003	Gilbert Rene Gonzales	PEDI / 13	8069

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,408	GONZALES ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-50 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1- 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Wehling et al (US 5,223,264)

3. Wehling '264 discloses a method of administrating a effervescent tablets for children comprising pharmaceutically acceptable medicament contained with in aqueous dissolvable solid matrix, (see column 3, lines 18-25). Wehling also discloses the pharmaceutically active ingredients of medicaments include without limitations , antacids, analgesics, antiinflammatories, antibiotics, laxatives, anorexics, antiasthmatics, antidiuretics, antiflatuents, antimigraine agents, antispasmodics, sedatives, antihyperactives, tranquilizers, antihistamines, decongestants, betablockers, antialocholism agents, cough suppressants, fluoride supplements, antiseptics, and combination thereof. The combination of drugs that are typically administrated together may be included as the drug component of the pharmaceutical composition, (see,

column 4, lines 5-45). Wehling further discloses the composition of medicament comprising of binding agents with in the matrix such as starch, gelatin, acacia, tragaacanth, cellulose materials such as methyl cellulose and sodium carboxy methyl cellulose, alginic acids and salts thereof, magnesium aluminum silicate, polyethylene glycol, guar gum, polysaccharide acids, bentonites, sugars, invert sugars and the like. Binders may be used in an amount of up to 60 weight percent and preferably about 10 to about 40 weight percent of the total composition, (see column 6, lines 49-64). Wehling also discloses the effervescent disintegration agent(s) comprising a soluble acid component and a alkali metal carbonate. The reaction of these two general classes of compounds produce carbon dioxide, oxygen or other gases (which are pediatrically safe) upon contact with water include in saliva or simply gastric fluids. The amount of either acid or carbonate source is equivalent/ acid or carbonate source may exceed the amount of the other component in acceptable range as claimed (see column 5, lines 4-58). Wehling also discloses the size and shape of the tablets adopted for direct oral administration to children. The tablets include surface markings, cuttings, grooves, letters and or numerals for the purpose of easy consumption by child (see column 3, lines 43-63). Wehling also discloses a process of administrating intended ingredient medicament to a child, so that tablet disintegrate in the child's mouth to provide a controlled drug delivery system and increased absorption of drug, (see column 3, lines 29-39)

4. Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Talwar et al (US 6,261,601).

5. Talwar '601 discloses the pharmaceutical composition of drug. The amount of drug to be used in the composition is that which is typically administrated for a given period of time. The amount of drug typically ranging from about 0.5 mg up to about 1200 mg (see column 7, lines 32-39)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for various inert gases such as carbon dioxide, nitrogen, air, helium and oxygen, which can be treated as harmless in nature, does not reasonably provide enablement for toxic ethylene oxide gas as broadly claimed in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth here in below.

The specifications provide no sufficient experimental details for generating ethylene oxide gas as one of the component of inert gas.

The specifications provide no guidance or information of toxic nature of ethylene oxide gas. It is well known in the literature, that ethylene oxide is highly toxic and lead to many unwanted side effects (The main source of information for this facts is the Agency for Toxic Substances and Disease Registry's (ATSDR'S) Toxicology Profile for Ethylene Oxide. Other secondary sources include the Hazardous Substances Data bank (HSDB), a database of summaries of peer-reviewed literature, and the Registry of Toxic Effects of Chemical sub (RTECS), a database of toxic effects that are not peer reviewed).

The specifications provide no evidence of working example that containing ethylene oxide gas as one of the component of inert gas.

The claimed invention relates to effervescent disintegration agents comprising of a soluble acid component and an alkali metal carbonate generally produces inert gases such as carbon dioxide, nitrogen, air, helium, ethylene oxide and oxygen upon contact with water include in saliva or simply gastric fluids. Given the known advantages of inert gases in literature (oxygen, carbon dioxide, nitrogen, helium and air) the

unpredictability of presence for ethylene oxide gas as one of the component in the medicament, has a number of side effects, as discussed hereinafter.

Ethylene oxide possesses several physical and health hazards that merit special attention. Acute exposures to ethylene oxide gas may result in respiratory irritation and lung injury, headache, nauseas, vomiting, diarrhea, shortness of breath, and cyanosis. Also chronic exposure has been associated with the occurrence of caner, reproductive effects, mutagenic changes, neurotoxicity, and sensitization.

Thus the presence of carcinogenic gas as one of the component is predicted to be highly dangerous for its use. The specification does not enable any person skilled in the art to which it pertains, or to use the invention commensurate in scope with these claim.

The claims are very broad and inclusive of treating various diseases. The medicament used for the treatment of these diseases employed different agents in combinations as specified thereof.

The nature of claims is an oral pharmaceutical medicament enable for using towards various treatments as set forth. Especially the claims and /or specification fail to provide a teaching on how to limit the ethylene oxide gas to avoid its known toxicity.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER